UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Marsha Flight, Individually, and
Ronald Flight, Individually

vs. Case No. _____

CIVIL ACTION

Defendants
American Medical Systems, Inc., and Caldera Medical, Inc.

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs Marsha Flight and Ronald Flight, (alternatively referred to as "Plaintiffs"), by and through the undersigned attorneys, sue American Medical Systems, Inc., and Caldera Medical, Inc. (alternatively referred to as "Defendants").

PARTIES, JURISDICTION AND VENUE

1. Plaintiffs are citizens of the State of Ohio.

2. Defendant American Medical Systems, Inc. ("AMS") is a corporation and is incorporated under the laws of the State of Delaware, with its corporate headquarters in Minnetonka, Minnesota. All acts and omissions of Defendant as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

3. Defendant Caldera Medical, Inc. ("Caldera") is a corporation and is incorporated under the laws of the State of California, with its corporate headquarters in Agoura Hills, California. All acts and omissions of Defendant as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

4. Jurisdiction is proper under 28 U.S.C. §1331 because the parties are diverse and the plaintiffs are seeking damages in excess of $75,000.00.

5. Defendant has significant contacts with and conducts business in the District of Minnesota, where Defendant's corporate headquarters are located, and pursuant to 28 U.S.C. §1391(a), venue is proper in the District of Minnesota.

BACKGROUND

6. At all relevant times, AMS was engaged in the business of designing, manufacturing, testing, packaging, labeling, promoting, distributing and selling medical devices, including the MONARC™ hammock, for the treatment of stress urinary incontinence.

7. The MONARC™ hammock was originally approved for sale and use by the FDA in 2005. The FDA's decision for approval was based upon information provided to them by AMS.

8. At all relevant times, Caldera was engaged in the business of designing, manufacturing, testing, packaging, labeling, promoting, distributing and selling medical devices, including the T-Sling®, for the treatment of stress urinary incontinence.

9. The T-Sling® was originally approved for sale and use by the FDA in 2006. The FDA's decision for approval was based upon information provided to them by Caldera.

10. On or about July 2, 2008, Marsha Flight underwent surgery at The Surgery Center at Akron General Health and Wellness in Akron, Ohio and was implanted with the MONARC™

hammock.

11. Soon thereafter, Plaintiff Marsha Flight began to experience severe pelvic pain, chronic infections, and other debilitating side effects. Mrs. Watkins suffered, and continues to suffer, pain and discomfort.

12. On or about September 3, 2008, Marsha Flight underwent surgery at The Surgery Center at Akron General Health and Wellness in Akron, Ohio and was implanted with the T-Sling®.

13. Soon thereafter, Plaintiff Marsha Flight began to experience severe pelvic pain, chronic infections, and other debilitating side effects. Mrs. Watkins suffered, and continues to suffer, pain and discomfort.

STATEMENT OF THE CLAIM

Count I: Strict Liability

7. At all relevant times, Defendants AMS and Caldera designed, manufactured, tested, assembled, packaged, labeled, promoted, distributed and sold the MONARC™ hammock and T-Sling® (collectively "Products"), respectively, and the Plaintiff, Marsha Flight, was the recipient of the Defendants' Products.

8. The Products were expected to and did reach the usual consumers, handlers, and persons coming into contact with the product without substantial change in the condition in which the Products were designed, manufactured, tested, assembled, packaged, labeled, promoted, distributed and sold by Defendants AMS and Caldera.

9. At those times, the Products were in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the plaintiffs. Plaintiffs contend that the defective condition of the Products and the lack of ordinary care in designing, manufacturing

and assembling the Products is obvious and within the range of comprehension of the average juror without speculation.

10. The Products, designed, manufactured, tested, assembled, packaged, labeled, promoted, distributed and sold by AMS and Caldera, were defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers, the foreseeable risk exceeded the benefits associated with the design or formulation of the Products.

11. The Products were being used in a manner reasonably anticipated at the time it was used for the treatment of stress urinary incontinence in the plaintiff, Marsha Flight.

12. The Products, at the time the products left the possession of AMS and Caldera, were inherently dangerous for their intended uses and were unreasonably dangerous products which presented and constituted an unreasonable risk of danger and injury to the plaintiffs as follows:

i. The MONARC™ hammock and T-Sling® were sold in a defective condition by design, manufacture and assembly;
ii. The MONARC™ hammock and T-Sling® as designed, manufactured and assembled were unsafe for the plaintiffs;
iii. The MONARC™ hammock and T-Sling® as designed, manufactured and assembled were unreasonably dangerous to the plaintiffs;
iv. The MONARC™ hammock and T-Sling® did not perform safely as ordinary consumers/patients, like the plaintiffs, would expect;
v. The MONARC™ hammock and T-Sling® as designed, manufactured and assembled was unsafe for its intended use; and
vi. AMS and Caldera failed to warn the end user about the dangers and risks of the product; and
vii. AMS and Caldera knew the component parts of the MONARC™ hammock and T-Sling® as implemented through design, manufacture and/or assembly could cause injury to the end user.

13. AMS and Caldera knew or should have known that the Products created a risk of unreasonable harm, dangerous side effects, including but not limited to, erosion, degradation, extreme pain in their users.

14. The Products were defective due to inadequate post-marketing surveillance and/or warnings because, after AMS and Caldera knew or should have known of the unreasonable, dangerous side effects, as well as other severe and permanent health consequences, the Defendants failed to provide adequate warnings and continued to market the product. The conduct of AMS and Caldera in continuing to market, sell and distribute the Products after obtaining knowledge that the product was failing and not performing as represented and intended showed complete indifference to or a conscious disregard for the safety of others, justifying an award of additional damages for aggravating circumstances in such a sum that will serve to deter AMS and Caldera from similar conduct in the future.

15. For all these reasons, AMS and Caldera have become strictly liable in tort to the plaintiffs for designing, manufacturing, testing, packaging, labeling, promoting, distributing and selling the Products for use in the treatment of female urinary incontinence.

16. The defects in the Products were a substantial factor in causing plaintiffs' injuries.

17. As a direct and proximate result, the plaintiffs suffered and will continue to suffer injuries and damages.

Count II: Breach of Express Warranty

18. AMS and Caldera expressly warranted that the Products were safe and/or well accepted by users.

19. The Products did not conform to these express representations because the Products were not safe and has numerous serious risks and side effects.

20. Plaintiffs relied on the express warranties of AMS and Caldera.

21. AMS and Caldera knew or should have known that its representations and warranties were false, misleading and untrue.

22. AMS and Caldera breached their express warranties because the Products were defective.

23. As a direct and proximate result of the acts and/or omissions of AMS and Caldera, the plaintiffs suffered and will continue to suffer injuries and damages.

Count III: Breach of Implied Warranties

24. At the time AMS and Caldera were designed, manufactured, tested, assembled, packaged, labeled, promoted, distributed and sold the Products, AMS and Caldera knew of the use for which the Products were intended and impliedly warranted the products to be of merchantable quality and safe and fit for use.

25. AMS and Caldera impliedly represented and warranted that the Products were safe and of merchantable quality, and fit for the ordinary purpose for which the product was sold.

26. Plaintiffs relied on the implied warranty of merchantability of fitness for a particular purpose.

27. The Products were injected into the stream of commerce by AMS and Caldera in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with the product without substantial change in the condition in which the Products were sold.

28. AMS and Caldera breached these implied warranties because their Products were not fit for their intended purposes and uses.

29. As a direct and proximate result of the acts and/or omissions of AMS and Caldera, the plaintiffs suffered and will continue to suffer injuries and damages.

Count IV: Fraudulent Misrepresentation

30. AMS and Caldera falsely and fraudulently represented to the plaintiff, the Food & Drug Administration (FDA) and the general public that the Products had been tested and found to be safe and effective for its intended use.

31. The representations made by AMS and Caldera were, in fact, false.

32. When these representations were made by AMS and Caldera, the defendants knew the representations to be false and willfully, wantonly and recklessly disregarded whether the representations were true.

33. The representations were made by AMS and Caldera with the intent of defrauding and deceiving the plaintiffs, the FDA and the general public.

34. At the time the representations were made by AMS and Caldera, and at the time that the plaintiff used the Products, the plaintiffs were unaware of the falsity of these representations and reasonably believed them to be true.

35. In reliance upon AMS and Caldera, the plaintiff, Marsha Flight, was induced to and did use the Products and, as a consequence, sustained severe and permanent personal injuries and is at risk for sustaining severe and permanent injuries in the future.

36. AMS and Caldera knew and were aware or should have known that the Products had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/ or sufficient warnings.

37. AMS and Caldera knew or should have known that the Products had a potential to, could, and would cause severe and grievous injury and that it was inherently dangerous.

38. AMS and Caldera brought the Products to the market, and acted fraudulently to the detriment of the plaintiffs.

39. As a direct and proximate result of fraudulent misrepresentations made by AMD and Caldera, the plaintiffs suffered and will continue to suffer injuries and damages.

Count V: Fraudulent Concealment

40. At all times during the course of this dealing between plaintiffs and AMS AND CALDERA, the defendant misrepresented that the Products were safe for their intended use.

41. AMS and Caldera knew or was reckless in not knowing that its representations were false.

42. In representations to the plaintiffs, the FDA and the general public, AMS and Caldera fraudulently concealed and intentionally omitted the following material information:

a. that the Products were not safe for its intended use;
b. that AMS and Caldera was aware of dangers with the Products;
c. that the Products were defective;
d. that the Products were manufactured negligently;
e. that the Products were manufactured defectively;
f. that the Products were manufactured improperly;
g. that the Products were designed negligently;
h. that the Products were designed defectively;
i. that the Products were designed improperly.

43. AMS and Caldera were under a duty to disclose to plaintiffs, the FDA and the general public the defective nature of the Products.

44. AMS and Caldera had sole access to material facts concerning the defective nature of the Products.

45. AMS and Caldera knew that the plaintiffs had no way to determine the truth behind its concealment and omissions.

46. Plaintiffs reasonably relied upon facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by AMS and Caldera.

47. As a direct and proximate result of fraudulent concealment by AMS and Caldera, the plaintiffs suffered and will continue to suffer injuries and damages.

Count VI: Violation of the Minnesota False Statement in Advertising Act, Consumer Protection Act, Unlawful Trade Practices Act, & the Uniform Deceptive Trade Practices Act

48. By reason of the conduct by AMS and Caldera as alleged in this complaint, AMS and Caldera violated the provisions of Minn. Stat. §§ 325F.67, 325F.69, 325D.13 and 325D.44 through the use of false and misleading advertising, representations, and statements.

49. AMS and Caldera engaged in a deceptive trade practices through a misrepresentation, omission or other practice that deceived or could reasonably be expected to deceive or mislead a person like Marsha Flight to her detriment. This conduct includes but is not limited to:

a. representing to the plaintiffs that the Products were safe, fit, and effective for its intended use, knowing that these representations were false, and concealing from the plaintiffs that the Products had a serious propensity to and did cause physical harm and injuries to users;

b. engaging in advertising programs designed to create the image, impression, and belief by consumers like the plaintiffs that the Products were safe for human use even though AMS and Caldera knew these representations to be false; and

c. issuing promotional literature deceiving potential users of the Products by relaying positive information while downplaying the known adverse and serious health effects and concealing material relevant information regarding the safety and efficacy of the product.

50. AMS and Caldera engaged in an unlawful practice by making false representations as to the characteristics, uses and benefits of the Products when the defendants knew or had reason to know that these representations were false.

51. As a direct and proximate result of the defendant's statutory violations, the plaintiff, Marsha Flight, was implanted with the Products. This would not have occurred had AMS and Caldera not issued false or misleading advertising, representations, and statements to induce the plaintiff to agree to the use of the Products.

52. As a direct and proximate result of violations, the plaintiffs suffered and will continue to suffer injuries and damages.

Count VII: Negligence

53. Defendants owed a duty to Plaintiffs to exercise ordinary and reasonable care in designing, manufacturing, testing, marketing, labeling, packaging, selling and/or distributing the Products, to use ordinary care in providing adequate warnings and instructions to Plaintiff Marsha Flight and her physician regarding the Products.

54. Defendants failed to exercise ordinary and reasonable care in designing, manufacturing, inspecting, testing, labeling, monitoring, promoting, distributing and selling the Products, and Defendants negligently failed to provide adequate warnings and instructions to Plaintiffs or to her physician regarding the Products.

55. As a direct and proximate result of Defendants' negligence, Plaintiff Marsha Flight suffered serious and permanent bodily injuries, experienced significant mental and physical pain and suffering, has required multiple surgeries, and has expended and will continue to expend large sums of money for medical care and treatment, has suffered and will continue to suffer economic loss and/or lost income, and has otherwise been physically, emotionally and economically damaged.

Count VIII: Loss of Consortium

56. As a proximate result of the injuries and losses sustained by his wife/spouse Marsha Flight, Plaintiff, Ronald Flight, has been and will continue to be deprived of her love, companionship, affection, society, consortium, comfort, marital relations, services and support which he previously received.

57. This Plaintiff, Ronald Flight, has rendered and will for the indefinite future be required to render nursing care, medical and other services to his wife/spouse in connection with and due to her injuries.

Injuries and Damages

58. As a direct and proximate cause of defendant's negligence, Plaintiff Marsha Flight has suffered injuries that have had, and for the remainder of plaintiff's life will have, devastating consequences on her life and well-being. As a result of the defendant's negligence, Marsha Flight has suffered great physical and mental pain and anguish, disfigurement and impairment and loss of earning capacity. In all reasonable probability the plaintiff will continue to suffer in this manner for the balance of her natural life and she seeks damages for such injuries.

59. As a further result of the defendant's negligence, Marsha Flight has required extensive medical, nursing, and hospital expenses. As a further result of the injuries sustained by the Marsha Flight, there is a reasonable medical probability that she will require further medical care and attention and will incur future reasonable and necessary expenses for such medical care and attention. Plaintiffs seek all unliquidated and all other damages, as allowed by law, within the jurisdictional limits of this Court.

REQUEST FOR RELIEF

Plaintiffs ask that the defendant be cited to appear and answer and that plaintiffs have judgment against the defendant for:

a. Actual damages within the jurisdictional damages as allowed by law;

b. Punitive and/or exemplary damages as pled in this complaint;

c. Prejudgment and post-judgment interest as allowed by law;

d. Costs of suit;

e. Attorneys' fees; and

f. All other relief the Court deems appropriate.

Date: July 1, 2011

Respectfully submitted,

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